# POLICY AND PROCEDURES RELATED TO COMPLETION OF LABORATORY NOTEBOOKS

#### I. Policy

It is the Policy of Inc. to insure that Laboratory Notebooks are kept in such a manner as to secure adequate Patent-Rights, to maintain an accurate, consistent record of the Scientist's work by grant or contract, and to keep a sufficiently complete record that another Scientist can understand and reproduce the work and that there is a witness who can give corroborating testimony if needed and to insure that Laboratory Notebooks are secured daily to prevent the loss or theft of same.

#### II. Definitions

- A. <u>Scientist</u>: A Scientist is an individual employed or retained as a consultant or independent contractor to perform and document scientific research for . Inc.
- B. Grant: A Grant is a financial assistance mechanism whereby money and/or direct assistance is provided by Government Agency to carry out approved activities. A Grant is used whenever the awarding Agency anticipates no substantive programmatic involvement with Inc. during the performance of the financially assisted activities. Grants can be classified on the basis of type of activity supported (research, training, service, etc.), degree of discretion allowed the awarding office (mandatory or discretionary), and/or the method of determining amounts of award (negotiated basis or formula).
- C. <u>Contract</u>: A Contract is a written agreement between a third party and International, Inc. to perform scientific research for a stated purpose.

## III. Procedures for Maintaining Laboratory Notebooks

- A. Laboratory Notebooks shall be kept in a bound notebook. Loose records are easily challenged and hard to support because the dating cannot be tied to other contemporary records.
  - B. There shall be a separate Laboratory Notebook for each contract or grant.
- C. All entries in the Laboratory Notebook should be completed in permanent ink. Do not use pencil.
- D. A Master Log of all Laboratory Notebooks will be maintained by the Laboratory Manager for each Laboratory, and before starting a Laboratory Notebook, the Scientist shall advise the Laboratory Manager of the Contract and Title of the new Laboratory Notebook which shall be noted in the Master Log next to the next Laboratory Notebook number, and shall obtain the next number from the Laboratory Manager and record same in his new Laboratory Notebook.

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- E. When beginning a new Laboratory Notebook, the Scientist should record the Title of the Contract or Grant, the Contract or Grant Number, the Laboratory Notebook Number, in precise language the purpose and objective of your experiment and your general plan or procedure, and the date and time the experiment was begun.
- F. Experiments shall be recorded in chronological order. Skipped or blank pages or pages dated out of order create a suspicion of tampering with the record.
- G. Errors shall be crossed through with a single line and initialed. If the error is more than a few words, an explanation for the error should be noted in the margin where the error is corrected.
- H. All essential facts should be recorded, such as equipment use, conditions, times, materials used including source and quality, yields, characterizing data, and so on. Abbreviations and codes should be chosen and used in an unambiguous and consistent way and non-standard abbreviations and codes should be defined in the Laboratory Notebook before using same.
- I. The Scientist shall note the date and time when each experiment is started, and if work carries over more than one day, each succeeding day's entry shall reflect the time and date of same.
- J. The record of an experiment that takes more than one page should make definite references to previous and following pages so it can be followed, for example, "continued on p.\_", "continued from p.\_".
- K. If a standard or routine procedure is being followed, a reference to the location of a full description shall be made in the Laboratory Notebook.
- L. The record should draw conclusions, if possible. A conclusion may not be needed if the experiment is one of a routine series, but experiments that explore new conditions or are aimed at making a new composition should conclude with an evaluation of the results. This step is important because recognition of success is an important element in the reduction to practice of an invention. Unnecessary derogatory comments about the results should not be made -- the results may be valuable in a different way from what was anticipated when the experiment was started.
- M. Analytical or other test results should be attached or copied into the record, or if they are too bulky, reference should be made to where they can be found. Calculations that do not require formal recording should be made in the margin of the Laboratory Notebook.
- N. Any unused portion of a page should be struck out to forestall any challenge that the record has been augmented at a later date.

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- O. Enter all results, both good and bad. Copious descriptions with elaborate details are preferable. Better too much, than too little. Always keep in mind the necessity of original data to prove any new discoveries.
- P. When the record is complete, or when there will be some delay before the work will proceed, the Laboratory Notebook page should be signed and witnessed promptly. These signatures must be dated. The purpose of witnessing is to provide corroboration of the existence of the record at the date of signing by a person who can testify later, if needed. The reason is that an inventor's unsupported testimony on his or her behalf is considered under the law to be self-serving.
- Q. Witnessing should be done no more than a few days after the entries are made. Witnessing that is unduly delayed is a little better than no witnessing at all. Preferably, the witness should be someone who had observed and understood the experiments the laboratory technician may be a good witness but, in any event, the witness should have read and understood the entries and should be a person who can reasonably be expected to be available for several years after the date of signing. The witness should not be a potential co-inventor as he or she would probably be considered biased.
- R. Names of Operators and Witnesses who are present during a demonstration should be recorded. At least one witness, not claiming to be a co-inventor, should sign and date in the space provided at the bottom of the entry in the Laboratory Notebook. New concepts and new solutions to problems should be witnessed by your co-worker, or someone competent to understand the material being recorded. This fact should also be recorded, signed and dated.
- S. New ideas, plans, procedures, sketches, etc. should be recorded immediately in the Laboratory Notebook at the time they occur. These should be disclosed to, and understood by your co-workers who sign and date this fact.
- T. When an experiment shows results of possible patentable importance, and no witnesses are present, the procedure should be repeated under your supervision by your coworkers as soon as possible. Data covering the experiment should be recorded in both yours and his/her Laboratory Notebook with proper signatures and dates.
- U. In general, only one subject should be recorded on each page. Long Term projects should have separate books. All projects and experiments should be recorded in such a manner that any co-worker may continue the operation in your absence or upon your reassignment.
- V. Pages are provided for a Table of Contents. This should be completed as the experiment or project progresses to enable ready access to the contents in the future.

### IV. Procedures for Securing Laboratory Notebooks

A. All Laboratory Notebooks shall be kept under lock and key by the Laboratory Manager of each Laboratory when same are not in use by the Scientists.

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- B. The Laboratory Manager of each Laboratory will maintain a sign-in and sign-out log for all of the Laboratory Notebooks in his or her custody. Anyone wishing access or use of a Laboratory Notebook shall print his or her name on the sign-in and sign-out log, the date and time he or she took possession of the Laboratory Notebook and sign his or her name to the sign-in and sign-out log. When the Laboratory Notebook is returned to the Laboratory Manager, the Laboratory Manager shall line through the appropriate entry on the sign-in and sign-out log, and the person returning the Laboratory Notebook shall initial by the said line.
- C. Without the prior written permission of the President of no Laboratory Notebook will be removed from the premises of Inc.
- D. All Employees, Consultants and Independent Contractors of acknowledge the Laboratory Notebooks and all information recorded therein are the exclusive property of Inc. All Employees, Consultants and Independent Contractors of Inc. further acknowledge that all contents of the Laboratory Notebooks are to be held strictly confidential and must be returned upon completion, upon request or upon termination of employment for whatever reason. The person who had custody of a Laboratory Notebook must take every precaution to safeguard it against loss, damage or destruction. In case of fire, theft, damage or disappearance of a Laboratory Notebook, the Employee, Consultant or Independent Contractor will immediately notify the Laboratory Manager, or in the case that the Laboratory Manager has such knowledge, his or her Supervisor. A written report describing the circumstances of the loss, damage or destruction should follow.

READ AND UNDERSTOOD BY:		
Signature	Date	

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